REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 10, 12-14, 16, and 19-21 are pending in the present application. Claims 10 and 14 have been amended. Support for amended claim 10 can be found in the present specification at page 4, lines 9-20. Support for amended claim 14 may be found in the present specification at page 12, lines 1-16. The subject matter of claim 20 may be found in claim 10 and previously pending claim 11. Support for claim 21 may be found in claim 10 and previously pending claim 17. Claims 11 and 17 have been canceled.

In the outstanding Official Action, claims 10-14, 16, 17, and 19 were rejected under 35 USC §112, first paragraph, for allegedly not complying with the enablement requirement. Applicants believe the present amendment obviates this rejection.

In imposing the rejection, the Official Action alleged that the present specification did not enable claims directed to the prevention of the claimed conditions. However, the claims are now directed to a method of treating a mammal suffering from or at risk of suffering from obesity, being overweight, fluctuations in blood insulin levels, or fluctuations in blood glucose levels.

Claims 10-14, 16, 17, and 19 were further rejected under 35 USC §112, first paragraph, because the specification was allegedly not enabling for the treatment of any and all conditions. However, as noted above, the claims recite a method of treating a mammal suffering from or at risk of suffering from obesity, being overweight, fluctuations in blood insulin levels, or fluctuations in blood glucose levels. The claimed method comprises enterally administering to the mammal in need thereof an effective amount of a preparation containing glucose isomerase. As a result, the claims are not directed to any and all conditions, such as AIDS.

The Official Action also alleged that claim 14 was not enabled by the present disclosure. The Official Action alleged that the disclosure did not enable any and all carbohydrate absorption inhibitors and carbohydrase inhibitors. In the interest of advancing prosecution, claim 14 has been amended to recite specific carbohydrate absorption inhibitors and carbohydrase inhibitors.

As a result, applicants believe that this rejection has been obviated by the present amendment.

Indeed, at this time, the Examiner is respectfully reminded that it is a well- founded principle that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be

supported by evidence or reasoning substantiating the doubt so expressed. As a matter of law, the express teaching in the patent specification cannot be controverted by mere speculation and unsupported assertions on the part of the Patent Office. As stated by the Court of Customs and Patent Appeals in the case of *In re Dinh Nguyen and Stanhagen,* 181 USPQ 46 (CCPA 1974):

> Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed.

181 USPQ at 47.

Thus, such a standard must be applied with great care when the conjecture of the Patent Office is contrary to the teachings of the specification. When reviewing the Official Action, it is apparent that no evidence is adduced that is in any way consistent with the teachings of the present specification. As a result, applicants believe that the claims are fully enabled by the present disclosure.

Claims 10, 12, and 16 were rejected under 35 USC §102(b) as allegedly being anticipated by YING or SHIMIZU et al. This rejection is respectfully traversed.

Applicants believe that SHIMIZU et al. and YING both fail to disclose or suggest the claimed invention.

SHIMIZU et al. describe a hydrogel that can be used as a carrier for sustained release medicaments. The hydrogel is said to be suitable for entrapping drugs with a molecular weight of more than about 3000. At column 4, lines 21-28, examples of useful drugs are mentioned, including glucose isomerase. However, glucose isomerase is not mentioned anywhere else by SHIMIZU et al. Furthermore, lines 33-35 refer to various ways of using the hydrogel drug, i.e, as by injection, implant, oral administration, suppository or surgical use.

As a result, SHIMIZU et al. do not specifically disclose the oral administration of a hydrogel containing glucose isomerase. Furthermore, SHIMIZU et al. fail to provide any information as to the indications for which a hydrogel containing glucose isomerase could be used. SHIMIZU et al. do not disclose a method of treating obesity or fluctuations in blood insulin or blood glucose levels.

YING describes a method for administering an animal growth promoter to animals, the growth promoter comprises digestive enzymes selected from the group consisting of (1) protein digesting enzymes, (b) carbohydrate digesting enzymes, (c) fat digesting enzymes, and (d) fiber digesting enzymes. Glucose isomerase is mentioned (column 2, line 6) as an example of a carbohydrate digestive enzyme.

The Official Action contends that YING teaches that glucose isomerase can be administered orally to a patient. However, it is noted that YING is concerned with promoting growth in animals, whereas the present application is concerned with treating or preventing obesity or fluctuations in blood insulin or blood glucose levels. Thus, it is believed that the teachings of YING actually teach away from the claimed invention.

Thus, applicants believe that the SHIMIZU et al. and YING publications both fail to anticipate the claimed invention.

Claims 10-14, 16, 17 and 19 were rejected under 35 USC §103(a) as allegedly being unpatentable over SHIMIZU et al., taken with TSUJINO and CAREY et al. '358 and CAREY et al. '508. This rejection is respectfully traversed.

Applicants believe that the propose combination of SHIMIZU et al., in view of TSUJINO and CAREY et al. '358 and CAREY et al. '508, fails to render obvious the claimed invention.

According to the Official Action, the present claims are unpatentable under 35 USC §103 in view of SHIMIZU et al., taken with TSUJINO, CAREY et al. '358 and CAREY et al. '508. The Official Action alleges "Shimizu teaches that glucose isomerase can be administered orally to a patient suffering from diabetes".

However, diabetes is only mentioned once by SHIMIZU et al. in Example 9. Example 9 discloses a hydrogel containing insulin and describes the effect of injecting such a hydrogel on

blood sugar levels in alloxan diabetes rabbits. Consequently, SHIMIZU et al. effectively teach injecting insulin in the form of a hydrogel to patients suffering from diabetes. SHIMIZU et al. do not provide any suggestion to administer glucose isomerase to patients suffering from diabetes, let alone to administer such glucose isomerase orally. As noted above, SHIMIZU et al. fail to disclose or suggest any information related to the indications for which a hydrogel containing glucose isomerase could be used. Moreover, as the Examiner is aware, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). As the cited publications fail to suggest the claimed conditions, applicants believe that the publications, alone or in combination with each other fail to teach the claimed invention.

In an effort to remedy the deficiencies of SHIMIZU et al., the Official action cites TSUJINO and the CAREY et al. publications. However, TSUJINO relates to medicaments that comprise and enter a coding, including coded medicaments containing enzymes. TSUJINO does not describe or suggest the use of glucose isomerase, nor does the document describe or suggest the use of enzymes in a method for the treatment or prevention of

obesity, overweight, fluctuations in blood insulin levels, and/or fluctuations in blood glucose levels in mammals.

Both CAREY et al. publications relate to a composition containing a drug in a biocompatible, water soluble amphiphilic steroid capable of increasing drug permeability of body surface across which the drug is administered. The CAREY et al. publications mention isomerases but do not describe, suggest, or even mention glucose isomerase.

As a result, applicants believe that even if one of ordinary skill in the art were to combine these publications, one skilled in the art would still not obtain the claimed invention. Thus, applicants believe that the proposed combination of SHIMIZU et al., in view of TSUJINO and the CAREY et al. publications, fails to render obvious the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 10, 12-14, 16 and 19-21, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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